

AMENDMENTS TO THE CLAIMS

Applicant has submitted a new complete claim set showing marked up claims with insertions indicated by underlining and deletions indicated by strikeouts and/or double bracketing.

1. (Original) A method for treating a subject having, or at risk of developing, a cancer, comprising:

administering to a subject in need of such treatment a poly-G nucleic acid and a cancer medicament in an effective amount to treat the cancer or to reduce the risk of developing the cancer,

wherein the poly-G nucleic acid is not conjugated to the cancer medicament.

2. (Original) The method of claim 1, wherein the cancer medicament is selected from the group consisting of a chemotherapeutic agent, an immunotherapeutic agent, and a cancer vaccine.

3. (Original) The method of claim 2, wherein the chemotherapeutic agent is selected from the group consisting of methotrexate, vincristine, adriamycin, cisplatin, non-sugar containing chloroethylnitrosoureas, 5-fluorouracil, mitomycin C, bleomycin, doxorubicin, dacarbazine, taxol, fragyline, Meglamine GLA, valrubicin, carmustaine and poliferposan, MMI270, BAY 12-9566, RAS famesyl transferase inhibitor, famesyl transferase inhibitor, MMP, MTA/LY231514, LY264618/Lometexol, Glamolec, CI-994, TNP-470, Hycamtin/Topotecan, PKC412, Valspodar/PSC833, Novantrone/Mitroxantrone, Metaret/Suramin, Batimastat, E7070, BCH-4556, CS-682, 9-AC, AG3340, AG3433, Incel/VX-710, VX-853, ZD0101, ISI641, ODN 698, TA 2516/Marmistat, BB2516/Marmistat, CDP 845, D2163, PD183805, DX8951f, Lemonal DP 2202, FK 317, Picibanil/OK-432, AD 32/Valrubicin, Metastron/strontium derivative, Temodal/Temozolomide, Evacet/liposomal doxorubicin, Yewtaxan/Paclitaxel, Taxol/Paclitaxel, Xeload/Capecitabine, Furtulon/Doxifluridine, Cyclopax/oral paclitaxel, Oral Taxoid, SPU-077/Cisplatin, HMR 1275/Flavopiridol, CP-358 (774)/EGFR, CP-609 (754)/RAS oncogene inhibitor, BMS-182751/oral platinum, UFT(Tegafur/Uracil), Ergamisol/Levamisole, Eniluracil/776C85/5FU enhancer, Campto/Levamisole, Camptosar/Irinotecan, Tumodex/Ralitrexed, Leustatin/Cladribine, Paxex/Paclitaxel, Doxil/liposomal doxorubicin,

Caelyx/liposomal doxorubicin, Fludara/Fludarabine, Pharmarubicin/Epirubicin, DepoCyt, ZD1839, LU 79553/Bis-Naphtalimide, LU 103793/Dolastain, Caetyx/liposomal doxorubicin, Gemzar/Gemcitabine, ZD 0473/Anormed, YM 116, Iodine seeds, CDK4 and CDK2 inhibitors, PARP inhibitors, D4809/Dexifosamide, Ifes/Mesnex/Ifosamide, Vumon/Teniposide, Paraplatin/Carboplatin, Plantinol/cisplatin, Vepeside/Etoposide, ZD 9331, Taxotere/Docetaxel, prodrug of guanine arabinoside, Taxane Analog, nitrosoureas, alkylating agents such as melphelan and cyclophosphamide, Aminoglutethimide, Asparaginase, Busulfan, Carboplatin, Chlorombucil, Cytarabine HCl, Dactinomycin, Daunorubicin HCl, Estramustine phosphate sodium, Etoposide (VP16-213), Floxuridine, Fluorouracil (5-FU), Flutamide, Hydroxyurea (hydroxycarbamide), Ifosfamide, Interferon Alfa-2a, Alfa-2b, Leuprolide acetate (LHRH-releasing factor analogue), Lomustine (CCNU), Mechlorethamine HCl (nitrogen mustard), Mercaptopurine, Mesna, Mitotane (o.p'-DDD), Mitoxantrone HCl, Octreotide, Plicamycin, Procarbazine HCl, Streptozocin, Tamoxifen citrate, Thioguanine, Thiotepa, Vinblastine sulfate, Amsacrine (m-AMSA), Azacitidine, Erthropoietin, Hexamethylmelamine (HMM), Interleukin 2, Mitoguanzone (methyl-GAG; methyl glyoxal bis-guanyldihydrazone; MGBG), Pentostatin (2'-deoxycoformycin), Semustine (methyl-CCNU), Teniposide (VM-26) and Vindesine sulfate.

4. (Original) The method of claim 2, wherein the immunotherapeutic agent is selected from the group consisting of Ributaxin, Herceptin, Quadramet, Panorex, IDEC-Y2B8, BEC2, C225, Oncolym, SMART M195, ATRAGEN, Ovarex, Bexxar, LDP-03, ior t6, MDX-210, MDX-11, MDX-22, OV103, 3622W94, anti-VEGF, Zenapax, MDX-220, MDX-447, MELIMMUNE-2, MELIMMUNE-1, CEACIDE, Pretarget, NovoMAb-G2, TNT, Gliomab-H, GNI-250, EMD-72000, LymphoCide, CMA 676, Monopharm-C, 4B5, ior egf.r3, ior c5, BABS, anti-FLK-2, MDX-260, ANA Ab, SMART 1D10 Ab, SMART ABL 364 Ab and ImmuRAIT-CEA.

5. (Original) The method of claim 2, wherein the cancer vaccine is selected from the group consisting of EGF, Anti-idiotypic cancer vaccines, Gp75 antigen, GMK melanoma vaccine, MGv ganglioside conjugate vaccine, Her2/neu, Ovarex, M-Vax, O-Vax, L-Vax, STn-KHL theratope, BLP25 (MUC-1), liposomal idiotype vaccine, Melacine, peptide antigen vaccines,

toxin/antigen vaccines, MVA-based vaccine, PACIS, BCG vaccine, TA-HPV, TA-CIN, DISC-virus and ImmuCyst/TheraCys.

6. (Original) The method of claim 1, wherein the cancer medicament is a hormone therapy.
7. (Original) The method of claim 1, wherein the cancer medicament is taxol.
8. (Original) The method of claim 1, further comprising administering interferon- α to the subject.
9. (Original) The method of claim 1, wherein the cancer is selected from the group consisting of bone cancer, brain and CNS cancer, connective tissue cancer, esophageal cancer, eye cancer, Hodgkin's lymphoma, larynx cancer, oral cavity cancer, skin cancer, and testicular cancer.
10. (Original) The method of claim 1, wherein the immunostimulatory nucleic acid has a modified backbone.
11. (Original) The method of claim 10, wherein the modified backbone is a phosphorothioate modified backbone.
12. (Original) A method for treating a subject having or at risk of developing a cancer, comprising:
administering to a subject in need of such treatment, an immunostimulatory nucleic acid having a modified backbone and a cancer medicament selected from the group consisting of an immunotherapeutic agent, a cancer vaccine and a hormone therapy,
wherein the immunostimulatory nucleic acid is free of a CpG motif, and a T-rich motif.
13. (Original) The method of claim 12, wherein the immunostimulatory nucleic acid is a poly-G nucleic acid.

14. (Original) The method of claim 13, wherein the poly-G nucleic acid is not conjugated to the cancer medicament.

15. (Original) The method of claim 12, wherein the cancer medicament is taxol.

16. (Original) The method of claim 12, further comprising administering interferon- α to the subject.

17. (Original) The method of claim 12, further comprising administering a cancer antigen to the subject.

18.-20. (Canceled)

21. (Original) A method for preventing an allergic reaction in a subject receiving a blood transfusion, comprising
administering to a subject receiving a blood transfusion an immunostimulatory nucleic acid in an effective amount to prevent an allergic reaction to the blood transfusion.

22.-30. (Canceled)

31. (Original) A method for treating a subject having or at risk of developing cancer, comprising
administering to a subject in need of such treatment an immunostimulatory nucleic acid selected from the group consisting of a CpG nucleic acid and a non-CpG nucleic acid, and a cancer medicament that is a hormone therapy.

32.-35. (Canceled)

36. (Original) A device for delivering an immunostimulatory nucleic acid to a subject receiving an intravenous injection, comprising
an intravenous device selected from the group consisting of an intravenous bag and an intravenous tube, and an immunostimulatory nucleic acid,
wherein the immunostimulatory nucleic acid is coated on an internal surface of the intravenous device or is embedded within the intravenous device.

37. (New) A method for treating a subject having cancer comprising administering to the subject an immunostimulatory nucleic acid in a colloidal dispersion system, wherein the immunostimulatory nucleic acid is 8-100 nucleotides in length, and wherein the subject is receiving or has received radiation.

38. (New) The method of claim 37, wherein the immunostimulatory nucleic acid is a CpG nucleic acid.

39. (New) The method of claim 38, wherein the colloidal dispersion system is a liposome.

40. (New) The method of claim 39, wherein the immunostimulatory nucleic acid is administered following radiation.

41. (New) A method comprising administering an immunostimulatory nucleic acid in an implant to a subject that is receiving radiation, wherein the nucleic acid is 8-100 nucleotides in length.

42. (New) The method of claim 41, wherein the immunostimulatory nucleic acid is a CpG nucleic acid.

43. (New) The method of claim 41, further comprising stimulating an immune response in the subject.

44. (New) The method of claim 41, wherein the subject has cancer.

45. (New) The method of claim 44, wherein the cancer is basal cell carcinoma, biliary tract cancer, bladder cancer, bone cancer, brain cancer, CNS cancer, breast cancer, cervical cancer, choriocarcinoma, colon and rectum cancer, connective tissue cancer, cancer of the digestive system, endometrial cancer, esophageal cancer, eye cancer, cancer of the head and neck, gastric cancer, intra-epithelial neoplasm; kidney cancer, larynx cancer, leukemia, liver cancer, small cell lung cancer, non-small cell lung cancer, lymphoma, Hodgkin's lymphoma, Non-Hodgkin's lymphoma, melanoma, myeloma, neuroblastoma, oral cavity cancer, ovarian cancer, pancreatic cancer, prostate cancer, retinoblastoma, rhabdomyosarcoma, rectal cancer, renal cancer, cancer of the respiratory system, sarcoma, skin cancer, stomach cancer, testicular cancer, thyroid cancer, uterine cancer, cancer of the urinary system, as well as other carcinomas and sarcomas.

46. (New) The method of claim 41, wherein the nucleic acid is administered following radiation.

47. (New) The method of claim 41, wherein the nucleic acid is synthetic

48. (New) A kit comprising an immunostimulatory nucleic acid and a chemical/physical vector, wherein the nucleic acid is 8-100 nucleotides in length.

49. (New) The kit of claim 48, wherein the chemical/physical vector is an implant.

50. (New) The kit of claim 48, further comprising a cancer medicament, wherein the cancer medicament is a chemotherapy.

51. (New) A method of treating a subject with cancer comprising: administering at least one ligand for a pattern recognition receptor and a delivery vehicle; in conjunction with at least one cancer therapy wherein said method elicits a response in a subject disposed of cancer.

52. (New) The method of claim 51, wherein said cancer therapy comprises at least one

therapy consisting of hyperthermia therapy, radiation therapy, chemotherapy, photodynamic therapy (PDT), surgery, ultrasound, and focused ultrasound.

53. (New) The method of claim 52, wherein radiation therapy is introduced first.

54. (New) The method of claim 51, wherein the pattern recognition receptor ligand comprises a nucleic acid molecule.

55. (New) The method of claim 51, wherein the delivery vehicle comprises a liposome.

56. (New) The method of claim 51, wherein the delivery vehicle comprises a non-liposomal delivery vehicle.

57. (New) A method comprising: coating a medical device with a composition comprising at least one ligand for a pattern recognition molecule receptor; and a delivery vehicle.

58. (New) The method of claim 57, wherein the medical device comprises an implanted device.

59. (New) The method of claim 58, wherein the implanted device consists of at least one of the following devices consisting of a catheter, a stent, a mesh repair material, a Dacron vascular prosthesis, an orthopedic metallic plate, a rod and a screws.

60. (New) The method of claim 57, wherein the delivery device comprises a sustained release particle and a delivery vehicle.

61. (New) The method of claim 60, wherein the delivery vehicle comprises a liposome.

62. (New) A method comprising: administering a composition comprising at least one

ligand for a pattern recognition molecule receptor; a delivery device; and radiation therapy to a subject.

63. (New) The method of claim 62, wherein a ligand for a pattern recognition molecule receptor comprises a ligand for a signaling pattern recognition receptor.

64. (New) The method of claim 62, wherein a ligand for a pattern recognition molecule receptor comprises a ligand for an pattern recognition receptor.

65. (New) The method of claim 62, further comprising augmenting an immune response in said subject.

66. (New) The method of claim 65, wherein augmenting an immune response comprises augmenting an immune response in a subject disposed of cancer.

67. (New) The method of claim 66, wherein cancer comprises at least one cancer selected from the group consisting of lung cancer, skin cancer, liver cancer, bone marrow cancer, brain cancer, renal cell cancer, ovarian cancer, breast cancer, prostate cancer, cancers of mesenchymal tissues, lymphoma and colon cancer.

68. (New) The method of claim 62, wherein radiation therapy is introduced first.

69. (New) The method of claim 62, wherein the ligand comprises a synthetic compound capable of binding a pattern recognition receptor.

70. (New) A kit comprising: a delivery container; a delivery device; at least one ligand for a pattern recognition receptor; and plus or minus an antigen; wherein said ligand is capable of eliciting an immune response in a subject.

71. (New) The kit of claim 70, further comprising one or more chemotherapy agents.